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WELSH & FLAXMAN LLC
2000 DUKE STREET, SUITE 100
ALEXANDRIA, VA 22314

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/734,671	FOERSTER ET AL.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 02/09/2009, amended claim(s) 49 is/are acknowledged. The current rejections of the claim(s) 49 is/are *withdrawn*. The following new and/or reiterated grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 49 is rejected under 35 U.S.C. 102(b) as being anticipated by Burton (US 3,741,198 issued 06/26/1973).

4. For claim 49, Burton discloses a delivery system for delivering marker material to a target site within a patient (Abstract, column 3 line 63 – column 6 line 57) (as best seen in Figures 1, 3, and 6), comprising *inter alia*:

- an elongate member (puncture needle 14) (column 4 line 66 – column 5 line 17 and column 6 lines 50-57) having a distal end (the insertion/inserted end of puncture needle 14 as best seen in Figures 1, 3, and 6), a discharge port in the distal end (the open distal end of puncture needle 14 as best seen in Figures 3 and 6) and an inner lumen (the inner lumen of puncture needle 14 as best seen in Figures 3 and 6)

extending therein to and in fluid communication with the discharge port in the distal end (as best seen in Figures 3 and 6);

- a plurality of small beads or pellets (28) of radiodense material disposed within the inner lumen of the elongate member (as best seen in Figures 3-4) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17) and configured for deployment as a marker material (28) (as best seen in Figures 3-4) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17); and
- an ejector (the syringe positively recited in column 5 lines 12-15) which is advancable with and coupled to said elongate member (column 5 lines 12-15) and which is configured to eject the plurality of small beads or pellets comprising marker material from the discharge port in said distal end of said elongate member (the injection of the marker material through the puncture needle via use of the syringe as positively recited in column 5 lines 12-15) to mark a desired site for relocation (the spinal column is marked with the marker material for relocation during X-ray examination and/or fluoroscopic examination, column 5 lines 18-29).

Response to Arguments

5. Applicant's arguments filed 02/09/2009 have been fully considered but they are not persuasive. Applicant argues the anticipatory rejection of claim 49 under 35 U.S.C. 102(b) as being anticipated by Burton.

6. Specifically applicant argues, Burton does not disclose, teach, and/or fairly suggest the following:

a) “a plurality of small beads or pellets of radiodense material deployed as a marker disposed within the inner lumen”;

b) “Burton fails to disclose marker material”; or

c) “Burton discloses a radiopaque ferrofluid, which is injected to increase the radiopaqueness of body systems where there is slow flow of fluids, to permit radiological examinations by creating a contrast during X-ray procedures. In particular, the ferrofluid of Burton is injected into the spinal column and then is moved up and down the spinal column via a magnetic force to desired areas along the spinal column while taking radiographic images of the desired areas. A highly important aspect of Burton is that once the radiographic examination is completed, the ferrofluid is removed. The ability to completely remove the ferrofluid, thereby avoiding patient discomfort, is Burton's advancement over the prior art. As such, it is evident that ferrofluid of Burton is not used to mark a desired site for relocation and thus does not function as a marker as claimed.”

7. The Examiner disagrees, maintains the rejection as set forth and cited above, and in response notes the following:

8. In response to Applicant’s argument (a) and (b) that Burton fails to disclose, teach, and/or fairly suggest “a plurality of small beads or pellets of radiodense material deployed as a marker disposed within the inner lumen” or "a marker material", the Examiner notes as broadly as claimed Burton expressly discloses deploying a “marker” (as best seen in Figures 3-4) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17) comprising a “marker material” (as best seen in Figures 3-4) (column 3 line 63 –

column 4 line 17 and column 5 lines 8-17) comprising a plurality of ferromagnetic particles disposed within the inner lumen of an elongate member comprising a puncture needle (as best seen in Figures 3-4) (column 3 line 63 – column 4 line 17 and column 5 lines 8-17).

9. Burton states (see paragraph bridging columns 3-4):

"The method of preparing ferrofluids is known to those skilled in the art, however, to facilitate an explanation of this invention the process will be briefly described. Since most inorganic magnetic solids are characteristically insoluble in common liquids, the coupling of magnetic particles with the carrier liquid is accomplished by using a mordant-like material, which is initially applied to the particles of the magnetic material. The mordant-like material, or as it is often referred to as the stabilizer, has the ability to be both adsorbed onto the surface of the magnetic particles and also to solvate the carrier liquid. A typical compound of this type is oleic acid. The ferromagnetic particles which are used are relatively small being colloidal in size with diameters in the range of about 10 to 300 A (Angstroms) being most desirable. It should be appreciated that the term ferrofluid as utilized in this application is not limited to ferroliquids which contain iron, but is generic to all fluids which exhibit the above noted properties including liquids which contain metals other than iron which can effectively be moved by a magnetic force, such as chromium."

10. Moreover, Burton states (see column 4 line 58 – column 5 line 29):

"In order to more clearly explain the method of the present invention, specific attention will be directed to the drawings which show the method of this invention used for either radiographically or fluoroscopically examining the spinal column 10 of a patient 12. A sterile ferrofluid is prepared having a suitable liquid carrier such as a ferrofluid having a perflourinated aliphatic hydrocarbon liquid carrier and iron ferromagnetic particles. Sterile procedures are followed as is customary in conventional lumbar punctures. An 18 gauge lumbar puncture needle 14 is inserted between the third and fourth lumbar vertebrae into the subarachnoid space 16 of the cauda equina portion of the spinal column 10. The cauda equina is that portion of the spinal cord which continues as individual nerves extending beyond the spinal

cord proper 18. The cauda equina is surrounded by spinal fluid 20 and composed of distal nerve ends 22. The bevel 24 of the needle 14 is positioned in about the center of the cross sectional area of the subarachnoid space of the cauda equina. The stylet 26 is then removed and a predetermined amount, for example, 3 to 12 cc of spinal fluid is aspirated from the spinal column 10. A syringe (not shown) is used to inject approximately the same volume of ferrofluid 28 as the amount of spinal fluid removed into the cauda equina area of the subarachnoid space 16. The stylet 26 is reinserted into the needle 26 and a sterile dressing is placed over the needle assembly.

"As can be seen in FIG. 3, the ferrofluid 28 is hyperbaric as compared to the surrounding spinal fluid 20 and accordingly tends to settle to the lower side of the cauda equina in contact with the arachnoid membrane. The patient is now ready for the X-ray examination. The X-ray examination can be either a radiographic examination or a fluoroscopic examination depending upon the particular type of test results desired, but are usually used in combination. However, because of the advantages of the present method, the radiographic method requires less patient radiation exposure thus increasing patient safety."

11. Furthermore, absent any special definition in the instant Specification upon which Applicant does not appear to rely, the terms "marker" and "marker material" are being treated on the merits with their plain meaning consistent with the instant Specification. The term marker may be plainly defined as "something used as an indication" and the term "marker material" may be plainly defined as "a substance of which something used as an indication is made". Burton clearly discloses using the ferrofluid particles as a marked material indication of where the spinal fluid is to establish the location of the spinal fluid during X-ray examination and/or fluoroscopic examination (column 5 lines 18-29).

12. In response to Applicant's argument (c) that Burton fails to disclose, teach, and/or fairly suggest because Burton discloses "The ability to completely remove the

ferrofluid, thereby avoiding patient discomfort, is Burton's advancement over the prior art. As such, it is evident that ferrofluid of Burton is not used to mark a desired site for relocation and thus does not function as a marker as claimed." Reiterating, Burton clearly discloses using the ferrofluid particles as a marked material indication of where the spinal fluid is to establish the location of the spinal fluid during X-ray examination and/or fluoroscopic examination (column 5 lines 18-29).

13. Burton states (see column 5 line 18-29):

"As can be seen in FIG. 3, the ferrofluid 28 is hyperbaric as compared to the surrounding spinal fluid 20 and accordingly tends to settle to the lower side of the cauda equina in contact with the arachnoid membrane. The patient is now ready for the X-ray examination. The X-ray examination can be either a radiographic examination or a fluoroscopic examination depending upon the particular type of test results desired, but are usually used in combination. However, because of the advantages of the present method, the radiographic method requires less patient radiation exposure thus increasing patient safety."

Conclusion

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736